UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

EVERETT LABORATORIES, INC. Plaintiff, v. BRECKENRIDGUE PHARMACEUTICAL, INC. Defendant.	CIVIL ACTION NO. 08-3156 (JLL) **OPINION**

LINARES, District Judge.

Plaintiff Everett Laboratories, Inc. ("Everett") sued defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") for, inter alia, infringement of claims 2 and 4 of U.S. Patent No. 6,814,983 and U.S. Patent No. 7,390,509. Currently before the Court is Everett's motion for a preliminary injunction, filed June 26, 2008. The Court heard oral argument on August 7, 2008 and has reviewed the parties' submissions. For the reasons set forth herein, the Court grants Plaintiff's motion for a preliminary injunction.

I. Factual and Procedural History

Everett, a New Jersey-based pharmaceutical company that markets and sells prescription-only nutritional supplements and multivitamins, is the owner of U.S. Patent No. 6,814,983 ("the '983 patent"), issued November 9, 2004 and entitled "Compositions and Methods for Nutrition Supplementation." Everett is also the owner of U.S. Patent No. 7,390,509 ("the '509 patent" and together with the '983 patent, the "patents"), which issued June 24, 2008 and bears the same title as the '983 patent. The patents are directed to "compositions comprising vitamins and minerals

and methods for using these compositions for nutritional supplementation in . . . pregnant or lactating [women]." Claims 2 and 4 in the '983 and '509 patents cover Everett's drug at issue here, Vitafol-OB, a prescription-only prenatal nutritional supplement and multivitamin. Vitafol-OB contains specified quantities of various vitamins and minerals and is sold directly to drug wholesalers who in turn sell it to retailers, including pharmacies.

On June 5, 2008, Everett first discovered that Breckenridge, a company headquartered in Florida that markets low cost multivitamins and nutritional supplements, was selling Multifol Plus, a prescription-only prenatal nutritional supplement and multivitamin. Because Multifol Plus contains the same vitamins and minerals in the precise amounts as in Vitafol-OB, Everett contends that Multifol Plus is a "direct" or "knock-off" copy or a "generic" version of Vitafol-OB.[1] Moreover, Everett maintains upon information and belief that Breckenridge contacted First DataBank, one of the leading providers of electronic drug databases to the health care industry, to hold out Multifol Plus as a generic version of Vitafol-OB.

On June 24, 2008, Plaintiff filed a complaint against Breckenridge, alleging patent infringement of both the '983 and the '509 patents, violations of federal and state unfair competition laws as against the Lanham Act and the New Jersey Fair Trade Act, respectively, and copyright infringement. Two days later, Plaintiff filed a motion for preliminary injunction, seeking to enjoin Breckenridge from continuing to sell Multifol Plus. In response, to the motion,

[1] Despite the use of the term "generic" by the parties, the situation at bar is distinguishable from those cases cited herein because the products at issue here are not Food and Drug Administration ("FDA")-approved drugs and thus, are not subject to the Hatch-Waxman Act, 21 U.S.C. § 355.

Breckenridge claims that both the '983 and '509 patents are invalid.[2]

II. Standard of Review

Preliminary injunctions are extraordinary remedies that are not routinely granted. Nat'l Steel Car, Ltd. v. Canadian Pacific Ry., Ltd., 357 F.3d 1319, 1324 (Fed. Cir. 2004). The decision to grant a preliminary injunction is within the sound discretion of the district court. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391, 394 (2006); see Abbott Labs. v. Andrx Pharms., Inc., 452 F.3d 1331, 1334 (Fed. Cir. 2006); Amazon.com, Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001). The Court examines the following four factors in determining whether injunctive relief should be granted:

(1) whether the movant has shown a reasonable likelihood of success on the merits;

(2) whether the movant will be irreparably harmed by denial of the injunctive relief sought;

(3) whether the injury to the movant in the absence of injunctive relief outweighs the possible harm to the non-movant if the injunction is granted; and

(4) the impact of a preliminary injunction on the public interest.

See, e.g., Abbott Labs, 452 F.3d at 1334; Nat'l Steel Car, 357 F.3d at 1324-25.

The movant herein bears the burden of demonstrating that the injunction it seeks should issue. See, e.g., Abbott Labs., 452 F.3d at 1334. "[A] movant cannot be granted a preliminary injunction unless it establishes both of the first two factors, i.e., likelihood of success on the merits and irreparable harm." Amazon.com, 239 F.3d at 1350 (emphasis in original). However,

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[2] Breckenridge has not responded to Plaintiff's complaint due to the pending motion. The only invalidity arguments discussed in this Opinion are those raised by Defendant in its moving papers. Any arguments raised for the first time at the August 7, 2008 oral argument by either party will not be addressed as such arguments are not properly before the Court.

the Court must generally weigh all four factors in determining whether to grant an injunction. See id.; Novartis Corp. v. Teva Pharms. USA, Inc., Nos. 04-4473, 06-1130, 2007 WL 1695689, at *3 (D.N.J. June 11, 2007).

III. Discussion

A. Likelihood of Success on the Merits

In order to establish likelihood of success on the merits, Plaintiff must prove, in light of the presumptions and burdens applicable at trial, that (1) Breckenridge is infringing the asserted claims of the '983 and '509 patents and (2) the patents can withstand Breckenridge's claims of invalidity. See Tate Access Floors, Inc. v. Interface Architectural Res., Inc., 279 F.3d 1357, 1365 (Fed. Cir. 2002); Amazon.com, 239 F.3d at 1350. Breckenridge does not dispute infringement and thus, only the second inquiry is at issue here. With respect to said inquiry, it is Plaintiff's burden to show that Defendant's invalidity defenses lack substantial merit. See Abbott Labs., 452 F.3d at 1335. In other words, if Defendant raises a substantial question of invalidity, Plaintiff is not entitled to a preliminary injunction. See Abbott Labs., 452 F.3d at 1335; see also Amazon.com, 239 F.3d at 1350-51 (stating that if the patentee "raises a substantial question concerning either infringement or validity, i.e., asserts an infringement or invalidity defense that the patentee cannot prove 'lacks substantial merit,' the preliminary injunction should not issue"); cf. Erico Int'l Corp. v. Vutec Corp., 516 F.3d 1350, 1354 (Fed. Cir. 2008) (the alleged infringer "must show a substantial question of invalidity to avoid a showing of likelihood of success").

In making this determination, the Federal Circuit has emphasized that the district court's finding as to likelihood of success at the preliminary injunction stage is just that—preliminary. Specifically, the Federal Circuit has stated, "[v]alidity challenges during preliminary injunction

proceedings can be successful, that is, they may raise substantial questions of invalidity, on evidence that would not suffice to support a judgment of invalidity at trial." Amazon.com, 239 F.3d at 1358; see also Erico, 516 F.3d at 1355-56 (emphasizing that "a showing of a substantial question of invalidity requires less proof than the clear and convincing standard to show actual invalidity"); Novartis, 2007 WL 1695689, at *3 n.8 (indicating that a district court's finding that defendant has raised a substantial defense does not mean that the defendant will carry its burden at trial to prove invalidity based on clear and convincing evidence). "Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial." Amazon.com, 239 F.3d at 1359; see also Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc., Nos. 04-1689, 06-757, 2006 WL 3019689, at *2 (D.N.J. Oct. 23, 2006).

Breckenridge makes two claims of invalidity: first, that the patents are invalid as obvious under 35 U.S.C. § 103 (Def. Opp'n at 7) and second, that the '983 patent is invalid as failing to comply with its specification pursuant to 35 U.S.C. § 112 (id. at 14). The Court's consideration of both of these arguments follows.

1. Obviousness

A patent may not be obtained from the United States Patent and Trademark Office ("PTO") if the "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." 35 U.S.C. § 103(a). This is a legal question, based on the underlying factual determinations. See, e.g., PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342, 1359 (Fed. Cir. 2007). In evaluating the obviousness of a patent, courts look to the totality of the circumstances, including:

(1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of non-obviousness, i.e., secondary considerations such as commercial success, long-felt need, the failure of others, copying, respect by the industry via commercial acquiescence, acclaim, and unexpected results. Id. In deciding the question of obviousness, the Court must consider whether a person of ordinary skill in the art would have had a reason for attempting to make the composition at issue and whether he would have had a reasonable expectation of success in doing so. Id. at 1360; see Ortho-McNeil Pharm., 2006 WL 3019689, at *3.

In KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007), the Supreme Court recognized that almost all inventions "rely on building blocks long since uncovered" and therefore, are "combinations of what, in some sense, is already known." Id. at 1741. The Court thus concluded that a patent is not obvious simply because each of its elements was independently known in the prior art. Id. Instead, in evaluating whether the subject matter of a patent claim is obvious, courts must look at the objective reach of the claim and whether such extends to what is obvious. See id. at 1741-42. The KSR Court rejected a rigid and formalistic application of the Federal Circuit's "teaching, suggestion, and motivation" test, under which a patent claim was obvious if there was some motivation or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the art, to combine the prior art teachings as such were combined by the inventor. See id. at 1734, 1741; see also Crown Operations Int'l Ltd. v. Solutia Inc., 289 F.3d 1367, 1376 (Fed. Cir. 2002) (discussing the Federal Circuit's teaching, suggestion, and motivation test pre-KSR).

The Supreme Court indicated in KSR that in conducting an obviousness analysis, courts

must apply a common sense approach, looking at all of the circumstances, and considering any inferences or creative steps that a person of ordinary skill in the art would have employed to determine "whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue." KSR, 127 S. Ct. at 1740-42 (emphasis added). Furthermore, the KSR Court indicated that obviousness may be established by showing that a combination of elements was obvious to try. The KSR Court stated:

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance, the fact that a combination was obvious to try might show that it was obvious under § 103.

Id.

Breckenridge contends that the scope and content of the prior art are such that the patents were prima facie obvious at the time the PTO granted them. In particular, Breckenridge claims that (i) Everett introduced Vitafol-OB only after it had had a similar multivitamin on the market, Vitafol-PN, for a number of years, the original formula for which was disclosed in the 1997 Physician's Desk Reference ("PDR") and the revised formula, in the 1999 PDR,[3] (ii) five other prescription prenatal vitamins with formulas similar to Vitafol-OB were disclosed in the 1997 PDR: Prenate 90, Nestabs, Materna, Zenate and Precare (Def. Br. at 9 n.5; see also Def. Ex. D), and (iii) prior to December 2001, two other prescription prenatal multivitamins – Natalins and Prenate – were disclosed in the 1993 and 1997 PDRs, respectively, to have formulas comprising

[3] Breckenridge concedes, however, that while Vitafol-PN contained all the vitamins and minerals in Vitafol-OB, it did not contain copper, which is an ingredient in Vitafol-OB, and it did contain selenium, which is not in Vitafol-OB. (Def. Opp'n at 8.)

all of the vitamins and minerals of the claimed compositions of the '983 and '509 patents without any added vitamins or minerals.

Everett relies on the precise amount of the calcium contained in the patents coupled with the differing quantities of other vitamins and minerals as considered by the PTO to rebut Defendant's obviousness argument. (See Tr. at 7:19-7:22; 13:2-13:5; 13:18-13:24.)[4] Everett points out that the PTO considered said prior art during the prosecution of the patents and submits evidence to show that the PTO Examiner considered the US Recommended Daily Allowance ("US RDA"), the Vitafol-PN product insert, and three prior art products cited by Breckenridge – Vitafol-PN, Natalins, and Prenate Advance – in the prosecution of the patents in question. (See Certification of Robert J. Schoenberg in Reply ("Schoenberg Reply Cert."), Ex. 1 at 3:48-4:30, 4:65-5:7; id. at Ex. 2; id. at Ex. 3 at 2:59-2:67.) Everett further argues that it disclosed the other prior art cited by Breckenridge – Zenate, Natalins, Materna, Prenate 90, Prenate Ultra, Nestabs, and Precare – for the Examiner's consideration (see id. at Ex. 2), and that it is clear that Examiner Choi (and Supervisory Patent Examiner Richter) considered the obviousness of the combination of the vitamins and minerals – and the accompanying amounts – and concluded that the patents were not obvious. In fact, Everett asserts, Examiner Choi expressly stated,

> In at least because the teachings of the art would lead one of ordinary skill in the art to use amounts of calcium and magnesium in amounts far greater than that claimed, there is no teaching in the prior art which would lead one of ordinary skill in the art to arrive at the specific combination of vitamins and minerals in the claimed amounts or one or more pharmaceutical carriers in a composition to the exclusion of other combinations of vitamins and minerals and amounts and one or more pharmaceutical carriers in a composition.

[4] "Tr." refers to the transcript of the August 7, 2008 oral argument.

(Id., Ex. 4 at 4 (emphasis added).)

At oral argument, Breckenridge in essence urged the Court to reject the PTO's findings. It argued that since the prior art does not teach the use of calcium in amounts that could be considered "far greater" (see Tr. at 36:6-13:19), it must be surmised that although Everett "identified almost 50 patents to the Patent Office on the first application and a lot more on the second application" (id. at 35:7-35:8), the PTO may not have "formally reviewed and considered" all of them and thus, may have incorrectly reached the above-cited decision (id. at 35:10-35:12). Defendant also argues that Everett chose to reduce the amount of calcium because it reduced the size of the pill, making it easier to swallow. (Id. at 39:21-40:5.) Such an assertion is only conjecture: Defendant has not offered an expert opinion to buttress its claim (see id. at 40:7-40:8) or any other evidence that would tend to show (a) "design need" or "market pressure" for a smaller pill or (b) an "apparent reason" to create a smaller pill, see KSR, 127 S. Ct. at 1742. Moreover, in comparing the amounts of, inter alia, Vitamins A, C and B_{12} claimed in the patents with the amounts disclosed in the prior art, the Court finds significant variation between the patents and the prior art. (See Pl. Reply Br., App. 1 at Tables 1 & 2; Aug. 7, 2008 Pl. Exs. 1 and 2.) Without more from Breckenridge, and because the Court does not believe it prudent to second guess the findings of the PTO absent affirmative and definitive evidence contradicting said findings, the Court, at least at this stage in the litigation, defers to the PTO's decision of non-obviousness. See PharmStem, 491 F.3d at 1366 ("When the party asserting invalidity relies on references that were considered during examination or reexamination, that party bears the added burden of overcoming the deference that is due to a qualified government agency

presumed to have done its job" (emphasis added) (internal quotations omitted)).[5] Accordingly, the Court finds that Plaintiff has demonstrated for the purposes of the preliminary injunction it seeks that Defendant's obviousness argument is "without substantial merit."

Breckenridge claims that the differences between the invention and the prior art are slight in that the amounts of the vitamins and minerals contained in claims 2 and 4 of the '983 and '509 patents "encompass or overlap" those disclosed in the prior art.

An alleged infringer makes out a prima facie case of obviousness "when the ranges of a claimed composition overlap the ranges disclosed in the prior art." In re Harris, 409 F.3d 1339, 1341 (Fed. Cir. 2005). "Even without complete overlap of the claimed range and the prior art range, a minor difference shows a prima facie case of obviousness." Id. However, the patent holder may rebut the presumption of obviousness based on overlapping ranges if it demonstrates that (1) "the prior art taught away from the claimed invention" or (2) "there are new and unexpected results relative to the prior art." Iron Grip Barbell Co., Inc. v. USA Sports, Inc., 392 F.3d 1317, 1322 (Fed. Cir. 2004).

The key feature of the patents at issue – the amount of calcium – does not expressly fall within a range disclosed by prior art. Although Defendant argued that the known range of the prior art was between 125 mg and 1000 mg of calcium while the patents disclose a range of 90 mg to 110 mg (Def. Opp'n, App. 1 at 3), Plaintiff rebutted this claim with evidence that all

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[5] Where an alleged infringer challenges the patent's validity with an obviousness defense stating prior art already considered by the PTO, the infringer "bears an even heavier burden to prove invalidity." Metabolite Labs., Inc. v. Lab. Corp., 370 F.3d 1354, 1368 (Fed. Cir. 2004); see Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1375 (Fed. Cir. 2006) (noting that to the extent that the PTO already made a determination of non-obviousness, such made the defendant's burden of proving invalidity "especially difficult"); Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004).

known prior art, with the exception of its own Vitafol-PN, contains a minimum of 100 percent more calcium than the patents here (Pl. Reply Br., App. 1 at Table 3). Vitafol-OB contains 100mg of calcium while the next closest amount is the 125mg contained in Vitafol-PN. (Id. at Table 2.) All other prior art contains between 200 mg and 250 mg of calcium and the USRDA is 1000 mg. (Id.) The Court recognizes the slight overlap between the calcium range of the patents and the calcium range disclosed in the prior art, however it notes that "the range is disclosed in multiple prior art patents," see Iron Grip, 392 F.3d at 1322, and, guided by the Supreme Court's reasoning in KSR with respect to disclosure in multiple patents, see KSR, 127 S. Ct. at 1741, does not find that such overlap is prima facie evidence of obviousness in light of the other evidence before the Court.

Breckenridge also argues that one of ordinary skill in the art would be motivated to improve upon the already-existing prescription prenatal drugs, and points to two articles from July 1997 and May 2001 cited in the patents that state, "Optimizing specific nutrients before, during, and after the physiological processes of pregnancy and lactation can have a profound, positive, and comprehensive impact on the overall wellness of the developing and newborn child as well as the safety and health of the mother." ('983 Patent at 5:7-5:13; '509 Patent at 5:7-5:13.)[6] Plaintiff countered by asserting that "optimizing" merely meant to "put in nutrients that make the best product" or to "come up with a composition that will sell well in the market." (Tr.

[6] Neither party directs the Court to who a person of ordinary skill in the art is in this context. See Altana Pharma AG v. Teva Pharms. USA, Inc., 532 F. Supp. 2d 666, 676 (D.N.J. 2007) ("First, the Court must determine who is a person of ordinary skill in the art"). Notwithstanding this deficiency, the Court need only think of the person as "an objective legal construct who is presumed to be aware of all the relevant prior art." Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc., 456 F. Supp. 2d 644, 653 (D.N.J. 2006).

at 14:20-14:21, 15:8-15:9.) The Court's understanding of this argument is that the term "optimizing" is "too broad" to point one of ordinary skill in the art to choose the precise quantities of vitamins and minerals contained in Vitafol-OB, comprising the claims in the patents. The Court agrees: such general language, on its own, is insufficient to point one of ordinary skill in the art to select the amount of calcium and to adjust the quantities of the other vitamins and minerals comprising the patents.

Finally, the Court turns to the issue of objective indicia of non-obviousness, "often . . . the most probative and cogent evidence on the record" and possibly "sufficient to overcome a prima facie case of obviousness." See Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc., 456 F. Supp. 2d 644, 669 (D.N.J. 2006).

Everett contends that the secondary factors most relevant here are "commercial success" and "copying," specifically that Vitafol-OB's marketplace success raises a substantial question as to obviousness as does the fact that Multifol Plus is an illegal copy of Vitafol-OB. (Tr. at 5:10-5:12; 25:20-25:23.) For commercial success to evidence non-obviousness, the record must show a sufficient nexus between the success and the patented invention. Gambro Lundia AB v. Baxter Healthcare Corp., 110 F.3d 1573, 1579 (Fed. Cir. 1997). The Court finds that neither party presented the Court with evidence of the type of commercial success or the requisite "nexus" – or lack thereof – necessary to support a finding of obviousness or non-obviousness and thus, declines to consider this factor. See Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1394 (Fed. Cir. 1988). With respect to the issue of copying, the Court turns to the assertion and evidence before it that Multifol Plus contains the exact same vitamins and minerals in the exact same amounts as cited in claims 2 and 4 in the patents. (See Pl. Br. at 13.)

Breckenridge does not dispute that Multifol Plus is a copy of Vitafol-OB. Furthermore, the fact that Breckenridge is prepared to expend considerable sums in litigation expenses in order to continue to market and sell Multifol Plus is "powerful evidence of copying." See Ortho-McNeil Pharm., 2006 WL 3019689, at *9. Such objective indicia of non-obviousness taken in conjunction with the evidence discussed above further indicates that Plaintiff has met its burden of showing that Defendant's obviousness argument with respect to the '983 and '509 patents lacks substantial merit.

2. Written Description

Breckenridge claims that the '983 patent violates 35 U.S.C. § 112 as it does not contain an adequate written description. (Def. Opp'n at 14.)

Under 35 U.S.C. § 112, a patent specification must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . ." 35 U.S.C. § 112, ¶ 1. "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not . . . ." Amgen Inc. v. Hoechst Marion Roussel Inc., 314 F.3d 1313, 1330 (Fed. Cir. 2003). Thus, the specification must "teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quotations omitted). A person of ordinary skill in the art need only be aware that "the inventor possessed the invention at the time of th[e] original disclosure." Pandrol USA, LP v. Airboss Ry. Prods., Inc., 424 F.3d 1161, 1165 (Fed. Cir. 2005). However, the written description need not contain an exact description of the subject matter of the patent,

but only put persons of ordinary skill in the art on notice of what the patent claims. See id.; Eiselstein v. Frank, 52 F.3d 1035, 1038 (Fed. Cir. 1995).

Here, the specification discloses that the invention

> relates to compositions comprising various vitamins and minerals and methods for using these compositions for nutritional supplementation in, for example, subjects in physiologically stressful states. . . . [and] provides compositions and methods of using these compositions for both prophylactic and therapeutic nutritional supplementation, specifically throughout physiologically stressful states.
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> Specifically, for example, the present invention relates to novel compositions of vitamins and minerals that can be used to supplement nutritional deficiencies observed in patients throughout physiologically stressful states, such as, for example, pregnancy, lactation, and any disease state.

('983 patent at col. 1:7-1:10; 1:39-1:48.) At this preliminary stage, without any evidence in the record from experts, cf. Pandrol, 424 F.3d at 1166-67, the Court finds that the '983 patent meets the requirements of section 112 and that Plaintiff has satisfied its burden with respect to this argument.

Consequently, this Court finds that Plaintiff has made a clear showing of likelihood of success on the merits with respect to validity of both patents.

B. Irreparable Harm

Notwithstanding this Court's finding that Plaintiff has made a clear showing of likelihood of success on the merits with respect to the validity of both patents, Plaintiff still bears the burden of demonstrating that it will suffer irreparable harm in the absence of the preliminary injunction it seeks.

Cases in the past have applied a rebuttable presumption of irreparable harm where the plaintiff had made a clear or strong showing of probability of success on the merits. See

Amazon.com, 239 F.3d at 1350; Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1363 (Fed. Cir. 2001); Polymer Techs., Inc. v. Bridwell, H.A., 103 F.3d 970, 973 (Fed. Cir. 1996); see also Eli Lilly and Co. v. American Cyanamid Co., 82 F.3d 1568, 1578 (Fed. Cir. 1996). Breckenridge, however, argues that said presumption no longer exists in light of the United States Supreme Court's decision in eBay, Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

In eBay, the Supreme Court addressed district courts' practice of automatically issuing an injunction upon a finding of infringement and held that traditional principles of equity apply with equal force to disputes arising under the Patent Act. eBay, 547 U.S. at 392-93, 394. The Court stressed, "We hold only that the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts, and that such discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." Id. at 394 (emphasis added).

In the wake of this decision, the Federal Circuit has neither overruled its cases applying the presumption of irreparable harm nor offered an explicit directive on whether (1) to apply the presumption on a motion for a preliminary injunction or (2) the presumption exists at all. In Abbott Laboratories, a post-eBay decision, the Federal Circuit seemed to imply that the presumption may still exist at the preliminary injunction stage, stating, "[W]e conclude that [plaintiff] has not established a likelihood of success on the merits. As a result, [plaintiff] is no longer entitled to the presumption of irreparable harm." Abbott Labs., 452 F.3d at 1347.[7]

[7] Defendant argues that two recent Federal Circuit cases "indicate" that eBay applies to preliminary injunctions. The cases cited by Breckenridge, Erico Int'l Corp. v. Vutec Corp., 516 F.3d 1350 (Fed. Cir. 2008), and Chamberlain Group v. Lear Corp., 516 F.3d 1331 (Fed. Cir.

Subsequently, however, in a decision issued six months after Abbott Laboratories, the Federal Circuit skirted the question "[b]ecause [the Court] conclude[d] that the district court did not clearly err in finding that [plaintiff] Sanofi established several kinds of irreparable harm, including irreversible price erosion . . . ." Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1383 n.9 (Fed. Cir. 2006). Furthermore, the Federal Circuit took the same approach again this year. See Amado v. Microsoft Corp., 517 F.3d 1353, 1359 (Fed. Cir. 2008) (finding it "unnecessary to reach [plaintiffs's] argument [that the district court improperly found that eBay did away with the presumption of irreparable harm], however, because regardless of whether there remains a rebuttable presumption of irreparable harm following eBay, the district court was within its discretion to find an absence of irreparable harm . . ." (emphasis in original)).

District courts throughout the country have not arrived at a uniform interpretation of eBay in the context of a preliminary injunction, including those courts in this District. Compare Eisai Co., Ltd. v. Teva Pharms. USA, Inc., Nos. 05-5727, 07-5489, 2008 WL 1722098, at *10 (D.N.J. March 28, 2008) (Ackerman, J.) ("Presumably, if the Federal Circuit had read eBay as broadly as

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2008), only reinforce that the district court must examine all four factors in adjudicating a motion for preliminary injunction. See Erico, 516 F.3d at 1354 ("the district court applied the correct four factor test with emphasis on the 'likelihood of success'"); Chamberlain, 516 F.3d at 1335 ("the district court evaluated . . . the traditional four-factor test for injunctive relief"). Moreover, both decisions review a district court's grant of a preliminary injunction; in such instances, a district court must examine all four factors prior to issuing a preliminary injunction. See Polymer Techs., Inc. v. Bridwell, H.A., 103 F.3d 970, 973 (Fed. Cir. 1996). Thus, those cases cited by Defendant do not provide the Court guidance on this issue.

At oral argument, Defendant pointed the Court to Canon, Inc. v. GCC Int'l Ltd., 263 Fed. Appx. 57 (Fed. Cir. 2008), to further support its position that the eBay presumption no longer exists. (Tr. at 47:4-47:11.) Like Erico and Chamberlain, Canon merely applied the established four-factor test and did not directly address the continued existence of the presumption. However, the Court notes that Canon directly undercuts Defendant's position with respect to whether loss of market share constitutes irreparable harm. See note 10, infra.

[defendant] reads it, then the Abbott court would have noted at such a juncture that a presumption of irreparable harm no longer exists, period. Accordingly, this Court is loath to expand the Supreme Court's eBay decision to apply in such a manner . . . ." (emphasis in original)) with Novartis Pharms. Corp. v. Teva Pharms. USA, Inc., No. 05-1887, 2007 WL 2669338, at *13 (D.N.J. Sept. 6, 2007) (Cavanaugh, J.) (finding that eBay stands for the proposition that "on an application for a permanent injunction, a finding of patent infringement does not give rise to a presumption of irreparable harm," but concluding that "[s]ince . . . Plaintiff has [not] established a likelihood of success on the merits, [it] is not entitled to a presumption of irreparable harm").[8]

In its recent decision in Altana Pharma AG v. Teva Pharms. USA, Inc., 532 F. Supp. 2d 666 (D.N.J. Sept. 6, 2007) (Linares, J.), this Court took the same approach as the Federal Circuit and declined to make an explicit finding on the existence of the presumption, stating, "Such a presumption, if it is even still valid in light of *eBay*, would only be applied where a plaintiff makes a clear or strong showing of likelihood of success on the merits." Id. at 681-82 (emphasis added). The Court found that Altana had failed to make a showing of likelihood of success and consequently, the Court did not have to squarely address the question of whether the presumption

[8] One district court recently noted, "Despite the lack of clear direction from the Federal Circuit, the majority of district courts to directly analyze the issue have held that eBay did away with the presumption of irreparable harm in preliminary injunction cases involving patents." Voile Mfg. Corp. v. Dandurand, 551 F. Supp. 2d 1301, 1306 (D. Utah 2008) (collecting cases). But see Lennon v. Premise Media Corp., 556 F. Supp. 2d 310, 320 n.1 (S.D.N.Y. 2008); Eisai, 2008 WL 1722098 (D.N.J. 2008); Idearc Media Corp. v. Northwest Directories, Inc., No. 07-796, 2008 WL 2185334, at *9 (D. Or. May 23, 2008); Christiana Indus. v. Empire Elecs., Inc., 443 F. Supp. 2d 870, 884 (E.D. Mich. 2006). Furthermore, the Second and Ninth Circuits have applied the presumption post-eBay. See Time Warner Cable, Inc. v. DIRECTV, Inc., 497 F.3d 144, 162 (2d Cir. 2007); Abercrombie & Fitch Co. v. Moose Creek, Inc., 486 F.3d 629, 633 (9th Cir. 2007).

exists post-eBay. Id. at 682. The Court does not have the same luxury here since the Court has found that Plaintiff has preliminarily made a clear showing of likelihood of success. In the absence of explicit binding precedent, this Court remains reluctant to make a finding on the existence or absence of the presumption of irreparable harm. The Court need not make said finding since it will exercise its discretion "consistent with traditional principles of equity," and consider whether Plaintiff has met its burden to show irreparable harm. See eBay, 547 U.S. at 394. The Court concludes that Everett has.

Everett makes three main arguments in support of its claim of irreparable harm. Plaintiff contends that the presence of Multifol Plus on the market is causing price erosion of Vitafol-OB. Plaintiff further argues that the mechanism by which the third-party payor computer software automatically chooses Multifol Plus regardless of whether a physician prescribes Vitafol-OB or a generic alternative strips Plaintiff of its ability to compete in the market, resulting in lost sales and loss of market share. Finally, Everett claims that it will suffer irreparable harm to its goodwill and reputation and, as a consequence, will lose "brand recognition" of its entire line of Vitafol products. In response, Breckenridge argues that (i) economic loss in the form of price erosion, lost sales, and loss of market share does not constitute irreparable harm, (ii) the computer programs at issue do not cause irreparable harm because upon issuance of a permanent injunction against it, Multifol Plus would no longer be selected by said programs, and (iv) the goodwill and reputation argument is "speculative" and not supported by any evidence.

The Court finds Everett's argument with respect to loss of market share convincing, and agrees that the harm suffered by way of loss of market share cannot be quantified for the purposes of awarding money damages. (See Tr. at 28:24-29:20.) This Court also agrees that in

the context of this product and the marketing strategies involved it will be impossible to measure the amount of lost market share due to the presence of other competitive products on the market, i.e., Everett will not be able to know how much of the market share it lost due to the presence of a Vitafol-OB "generic" versus how much it lost to other prescription prenatal nutritional supplements and multivitamins–its competitors. (Id. at 29:11-29:20.) Everett indicates that the existence of Multifol Plus will cause Plaintiff to lose market share because of the "Hobson's choice" with which Plaintiff is presented: if Everett educates providers about Vitafol-OB and aggressively markets Vitafol-OB, providers subscribe Vitafol-OB only to promote greater sales for Mulitfol Plus because when Everett's product is prescribed, the third-party payor computer program picks the less expensive "generic." Thus, Everett must decide between indirectly promoting Multifol Plus or ceasing all promotion and marketing of its own product. (Id. at 16:3-16:8; 28:11-28:23.) The Court agrees that loss of market share is difficult to quantify in this context and thus, constitutes irreparable harm.[9] See Sanofi-Synthelabo, 470 F.3d at 1382

[9] The Court acknowledges that its position here is inapposite to its recent decision in Altana, where it found that loss of market share did not constitute irreparable harm for purposes of a preliminary injunction because such possible harm "would apply in every patent case where the patentee practices the invention." 532 F. Supp. 2d at 683 (quoting Nutrition 21 v. United States, 930 F.2d 867, 871 (Fed. Cir. 1991)). However, the Court finds the case at bar differs from Altana in that the patented product at issue here is not an FDA-approved drug and thus, not afforded the protections of the Hatch-Waxman Act. Under Hatch-Waxman, a drug has a period of exclusivity such that loss of market share is easy to quantify upon entry of one other generic drug into the market whereas in this instance, there is no exclusivity period and the market is already divided between the patented product and its competitors.

This case is further distinguishable. In Nutrition 21, the Federal Circuit continued on from the language quoted by this Court in Altana to say that the defendant there "[was] acknowledged to be a large and financially responsible company which would be answerable in damages." Id. (emphasis added); see also Boehringer Ingelheim Animal Health, Inc. v. Schering-Plough Corp., 984 F. Supp. 239, 263 (D.N.J. 1997) (finding no irreparable harm based on loss of market share because defendant "is a major drug company and will be able to compensate

(affirming the district court's finding that allegations of irreparable harm were sufficient to meet plaintiff's burden on the second prong where plaintiff argued that the price erosion based on the introduction of the generic drug – and the according third-party payor tier system – made it "nearly impossible to restore Plavix to its pre-launch price since the generic product entered the market").[10]

Everett's argument with respect to loss of goodwill further convinces this Court that Plaintiff will suffer non-quantifiable harm in the absence of a preliminary injunction.[11] Plaintiff

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[plaintiff] for any loss"). Here, Everett argues – and the Court agrees – that Breckenridge has not offered evidence of its ability or inability to remit money damages in the case of a judgment against it. While neither party presented ample evidence to the Court of Breckenridge's ability to pay damages, Breckenridge is indeed a "small business" (see Schoenberg Reply Cert., Ex. 6), and Breckenridgue failed to instill confidence in this Court that it would be able to pay any calculable damages in the absence of an injunction.

[10] Accord Canon, Inc., 263 Fed. Appx. at 62 ("Due to the difficulty (if not impossibility) of determining the damages resulting from price erosion and loss of market share, an award of money damages would not be sufficient"); Glaxo Group Ltd. v. Apotex, Inc., 64 Fed. Appx. 751, 756 (Fed. Cir. 2003) ("There is ample evidence in the record to show that allowing [defendant] to market its generic [ ] product would cause unquestionable loss of [plaintiff's] patent right . . . . [Plaintiff] . . . has shown that generic entry, even if not the first generic competition, would affect not only price and profit but also cause a significant loss of market share"); Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1368 (Fed. Cir. 2001) ("Given the testimony of the likelihood of price erosion and loss of market position without corresponding market expansion from the introduction of [defendant's] product, we see no deficiency in the district court's finding of irreparable harm"); cf. Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co., 290 F.3d 578, 595-96 (3d Cir. 2002) (affirming the district court's grant of a preliminary injunction and concluding that "loss of market share constitutes irreparable harm" in that "the sale of [defendant's product] had already had a measurable effect on [plaintiff's product's] market share as reflected by a decrease in sales of [plaintiff's product] that corresponds to increased sales for [defendant's product]").

[11] At oral argument, Plaintiff's counsel first discussed the problem of Breckenridge's "quality control" in conjunction with its alleged reputational harm. (See Tr. at 16:22-18:12; 29:21-30:3; 31:22-31:25.) While Plaintiff did indeed raise the reputation issue in its papers, it did not make specific allegations of Defendant's "quality control" problem. Because Plaintiff raised the specifics of this issue for the first time at oral argument, the Court will not consider it.

has spent considerable sums in researching, developing, marketing, and ensuring the success of Vitafol-OB. (Decl. of John A. Giordano in Support of Mot. for Prelim. Inj., ¶ 8.) However, as stated, Plaintiff contends that it is faced with a "Hobson's choice" of two undesirable options: (1) continue to expend tremendous resources to market Vitafol-OB such that it is prescribed only to have the third party payor system elect the cheaper, "generic" Multifol Plus when the prescription is filled or (2) stop marking Vitafol-OB completely to halt any indirect promotion of Multifol Plus. (Tr. at 16:3-16:8; 28:11-28:23.) This Court thus finds that without an injunction Plaintiff will suffer irreparable harm in the form of loss of goodwill as well. See Bio-Tech. Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 1566 (Fed. Cir.), cert. denied, 519 U.S. 911 (1996) (holding that the district court did not err in finding that plaintiff would suffer irreparable harm by way of "los[t] revenues and goodwill"); Genentech, Inc. v. Novo Nordisk A/S, 935 F. Supp. 260, 280-83 (S.D.N.Y. 1996), rev'd on other grounds, 108 F.3d 1361, 1368 (Fed. Cir. 1997) (concluding that loss of goodwill and a decrease in market share and revenue constitute irreparable harm).[12] Furthermore, the loss of market share in connection with the loss of

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See note 2, supra.

[12] See also Pappan Enters., Inc. v. Hardee's Food Sys., Inc., 143 F.3d 800, 805 (3d Cir. 1998) ("Grounds for irreparable injury include loss of control of reputation, loss of trade, and loss of goodwill"); CVI/Beta Ventures, Inc. v. Custom Optical Frames, Inc., 893 F. Supp. 508, 524 (D.Md. 1995) ("Irreparable harm has been found where a patentee's market representation and goodwill would not be fully compensated with money damages"); cf. Reebok Int'l Ltd. v. J. Baker, Inc., 32 F.3d 1552, 1558 (Fed. Cir. 1994) ("Harm to reputation resulting from confusion between an inferior accused product and a patentee's superior product is a type of harm that is often not fully compensable by money because the damages caused are speculative and difficult to measure").

goodwill demonstrates that Plaintiff has met its burden on the second prong of the inquiry.[13]

C. Balance of the Hardships and Public Interest

Since Plaintiff has met its burden on likelihood of success on the merits and irreparable harm, the Court will turn to the last two factors, i.e., the balance of the hardships and the public interest, in determining whether Plaintiff may be granted an injunction. See Polymer Techs., 103 at 973 ("[N]one [of the factors] may be ignored before granting a preliminary injunction" (internal quotation omitted) (emphasis in original)). The Court finds that both of these factors weigh in Plaintiff's favor.

1. Balance of the Hardships

Plaintiff argues that the balance of the hardships weighs in its favor because it has valid patents for a product whose sales and value are being diminished by the presence of Breckenridge's generic version of said product. Everett contends that Defendant cannot argue any harm because it made a "calculated risk to launch its willfully infringing product."

Everett maintains that Breckenridge would not be harmed in the face of preliminary injunction because it could still compete in the market with those drugs that do not infringe the '983 and '509 patents. Defendant does not argue harm. Instead, Defendant attempts to convince the Court that this factor does "not favor either party, because any potential harm to either party would be offset by an equal benefit to the other party." (Def. Opp'n at 25.)

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[13] Even if the Court had applied the presumption of irreparable harm here, Defendant did not present sufficient evidence to rebut the same. Certain types of evidence rebut the presumption of irreparable harm: (1) the non-movant will soon cease the allegedly infringing activities; (2) movants have engaged in a pattern of granting licenses under the patent (such that it is reasonable to expect that invasion of the patent right can be recompensated with a royalty rather than an injunction); and (3) movants unduly delayed in bringing suit. Polymer Techs., 103 F.3d at 974-75. Defendant has not presented evidence of any of these factors.

In instances where the patent owner will suffer diminution in the value of its patent, the balance of hardships weighs in the owner's favor. See Novartis Corp., 2007 WL 1695689, at *29- 31 (citing Glaxo Group Ltd., 64 Fed. Appx. at 756 ("The district court did not clearly err in finding that, without the preliminary injunction, Glaxo would lose the value of its patent while Apotex would only lose the ability to go on to the market and begin earning profits earlier.")); Ortho-McNeil Pharm., 2006 WL 3019689, at *10. Furthermore, any harms that Breckenridge may face due to the sale of its un-licensed drug are attributable to its own at-risk conduct. See Sanofi-Synthelabo, 470 F.3d at 1383 (affirming the district court's balance of the hardships in favor of the plaintiff, reasoning that "[Defendant's] harms were 'almost entirely preventable' and were the result of its own calculated risk to launch its product . . . ."). Thus, the balance of the hardships weighs in favor of Plaintiff.

2. Public Interest

Plaintiff argues that the issuance of a preliminary injunction would serve the public interest in enforcing "the efficacy of the U.S. patent system." Defendant counters that, in fact, the public interest weighs in favor of denying a preliminary injunction where a plaintiff has failed to establish a likelihood of success on the merits.

The Court must balance the public's interest in protecting patent rights, which encourage the development of useful inventions, with its interest in low cost generic alternatives to branded drugs. See Novartis, 2007 WL 1695689, at *31. The public interest favors enforcing a valid patent against an infringer. "[S]elling a lower-priced product does not justify infringing a patent." See Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1382 (Fed. Cir. 2005) (internal quotation omitted); Ortho-McNeil Pharmaceutical, 2006 WL 3019689, at *10; see also

Sanofi-Synthelabo, 470 F.3d at 1383-84 (holding that the district court did not err in finding that the public interest weighed in favor of encouraging pharmaceutical research and development as compared to the unavailability of lower cost generic drugs). Although public policy favors the entry – and availability of – low cost generic drugs in the market "it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents" or "excuse infringement of valid pharmaceutical patents." Pfizer, 429 F.3d at 1382. In this case, Defendant has implicitly conceded infringement, and Plaintiff has shown that Defendant's invalidity defenses lack merit. Considering the foregoing, the public interest also weighs in favor of Plaintiff. Thus, Plaintiff has met its burden on all four factors of the test.

IV. Conclusion

For the aforementioned reasons, the Court grants Plaintiff's motion for a preliminary injunction. Defendant Breckenridge is hereby preliminarily enjoined from continuing to sell or market Multifol Plus in the United States. An appropriate Order accompanies this Opinion.

Dated: August 26, 2008

/s/ Jose L. Linares
United States District Judge